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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/742,345	12/19/2003	Joelle Thonnard	GSKB-104US1	6249

26130 7590 12/12/2007  
RATNER & PRESTIA- SB DIVISION  
ONE WESTLAKES  
SUITE 301  
BERWYN, PA 19482

EXAMINER
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DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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12/12/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/742,345

Applicant(s)

THONNARD, JOELLE

Examiner

Patricia A. Duffy

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-8 and 11-18 is/are allowed.
- 6) ☒ Claim(s) 9, 10, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## RESPONSE TO AMENDMENT

The response filed amendment filed 9-26-07 has been entered into the record.

### *Objections/Rejections Withdrawn*

The use of the trademark TWEEN<sup>TM</sup> has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Claims 9, 10, 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the new grounds of rejection set forth below.

### *New Rejections*

Claims 9, 10, 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to immunogenic compositions comprising the nucleic acids of the invention. The current crafting of the claims requires the nucleic acid element of the claim to be the immunogenic moiety. The specification does not contemplate use of anti-nucleic acid antibodies or immune responses directed at the polynucleotides *per se* are effective for any purpose. The immune responses discussed in the specification are directed to use of the nucleic acid in expression vectors (live or plasmid) for the *in vivo* expression of the polypeptide, it is the polypeptide to which the immune response is directed, not the polynucleotide as claimed. The specification does not provide for any use for anti-nucleic acid antibodies, nor does it show that the polynucleic acid when administered by any means provides for an immune response. The polynucleic acid as claimed is incapable of producing the corresponding polypeptide because it lacks the necessary control sequences for polypeptide expression. While the specification discloses "gene immunization", the concept of gene immunization is an *in vivo* transcription of a nucleic acid in an appropriate expression vector to produce the polypeptide at specification paragraph [0076]. It is the polypeptide that is immunogenic and to which the immune response is directed, not the polynucleotide. The claims as currently crafted do not reflect this concept set forth in the specification as filed and argued by Applicant as an enabled embodiment. The specification does not provide for any use of anti-nucleic acid antibodies. The art does not recognize any use for anti-nucleic acid antibodies. The claims as drafted are directed to using the nucleic acids *per se* to generate an immune response

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to the nucleic acid. As such, this claimed embodiment is not enabled and has no disclosed use.

### *Status of Claims*

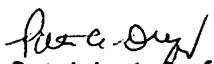
Claims 1-8 and 11-18 are allowed. Claims 9, 10, 19 and 20 stand rejected.

### *Conclusion*

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Shanon Foley can be reached on 571-272-0898.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

  
Patricia A. Duffy

Primary Examiner